PATENT COOPERATION TREATY

FEB 1 5 2001

From the INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: JANE MASSEY LICATA
LAW OFFICES OF JANE MASSEY LICATA
66 E. MAIN STREET
MARLTON, NEW JERSEY 08053

Docket System V
Status Report
Docket Book

NP=4-19-01

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing (day/month/year)

08 FEB 2001

Applicant's or agent's file reference

DEX-0052

IMPORTANT NOTIFICATION

International application No.

International filing date (day/month/year)

Priority Date (day/month/year)

PCT/US99/24331

18 OCTOBER 1999

19 OCTOBER 1998

Applicant

DIADEXUS LLC

- 1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
- 2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
- 3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US

Commissioner of Patents and Trademarks

Box PCT Washington, D.C. 20231

Pacsimile No. (703) 305-3230

Authorized officer

Porthe Faurence for

Telephone No. (703) 308-019

Form PCT/IPEA/416 (July 1992) *

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference			
DEX-0052	FOR FURTHER ACTION	See Notif Preliminar	ication of Transmittal of International y Examination Report (Form PCT/IPEA/416)
International application No.	International filing date (day	/month/year)	Priority date (day/month/year)
PCT/US99/24331	18 OCTOBER 1999		19 OCTOBER 1998
International Patent Classification (IPC) Please See Supplemental Sheet.	or national classification and	PC	
Applicant DIADEXUS LLC			
2. This REPORT consists of a This report is also accomplete amended and are the	total of sheets. panied by/ANNEXES, i.e., sheets sis for this report and/or sion 607 of the Administrative	according to	ription, claims and/or drawings which have
3. This report contains indication	s relating to the following	items:	
IV Lack of unity of i V X Reasoned statement citations and explar VI Certain documents of the company of t	t of report with regard to n nvention t under Article 35(2) with re nations supporting such states	gard to novelty nent	ive step or industrial applicability
Date of submission of the demand	Date	of completion	of this report
09 MAY 2000	1	9 JANUARY 2	2001
Name and mailing address of the IPEA/U Commissioner of Patents and Tradema. Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	rks	ofized officer OFFICE BEETHA P. BA Ohone No. (7)	Naurence Ga ANSAL

Form PCT/IPEA/409 (cover sheet) (July 1998) *

International application No.

PCT/US99/24331.

I. B	lasis of t	the report		
1. Wit	th regard	to the elements of the internation	and application #	
x		ternational application as ori		
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	pages _			, as originally filed
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	pages _	NONE	, filed with the letter of	
\mathbf{x}	the drav	wings:		
ننا	pages			inimally filed
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-	pages	NONE		as originally filed
	pages _	NONE		filed with the demand
	pages _	NONE	, filed with the letter of	
	the langu	guage of a translation furnish guage of publication of the is uage of the translation furnished	to this Authority in the following languageshed for the purposes of international search (uninternational application (under Rule 48.3(b)). End for the purposes of international preliminary examples.	under Rule 23.1(b)).
3. With	h regard t liminary	to any nucleotide and/or am examination was carried out	nino acid sequence disclosed in the international ton the basis of the sequence listing:	application, the international
		ed in the international applic	-	
			l application in computer readable form.	
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4. X		endments have resulted in th		
ļ	X the	e description, pagesNO	ONE	
إ	X the	e claims, Nos. NO	ONE	
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5.		• • • • • • • • • • • • • • • • • • • •	of) the amendments had not been made, since they l	the second and to an
	beyond the	the disclosure as filed, as indica	ated in the Supplemental Box (Rule 70.2(c)).**	_
676 67143	cement she	eets which have been furnished to	to the receiving Office in response to an invitation under not annexed to this report since they do not contain	er Article 14 are referred to amendments (Rules 70.16
	•	ent sheet containing such amer	ndments must be referred to under item 1 and anne	oved to this report

International application No. PCT/US99/24331

statement			
Novelty (N)	Claims	7	YE
	Claims	1-6	NO
Inventive Step (IS)	Claims	NONE	YE
	Claims	1-7	NO
Industrial Applicability (IA)	Claims	1-7	VP
11	Claims	NONE	YES

Claims 1-6 lack novelty under PCT Article 33(2) as being anticipated by Olsson et al (1997) and Cho-Chung et al (1993).

The claims are drawn to methods of diagnosing, staging and monitoring the metastatic potential of prostate cancer by identifying or detecting an increase in CSGs or cancer specific genes, in a patient. The claims are also drawn to a method of identifying therapeutic agents that bind to CSGs. Olsson et al teach the diagnosis, staging, monitoring metastasis of prostate cancer. Olsson et al teach that tumor cells exhibit abnormally rearranged or mutated genes that are not present in normal cells (these can be considered cancer specific genes). Olsson et al teach RT-PCR as well as quantitative RT-PCR technology as applicable to the above mentioned methods, and applying the technology to various tissue and body fluid samples. Cho-Chung et al teach the use of nucleic acid in the therapy of neoplasia with specific reference to anti-sense oligonucleotides.

The disclosure of Cho-Chung et al inherently teaches a method of identifying potential candidates that will bind to the CSGs in prostate cancer.

Claim 7 lacks an inventive step under PCT Article 33(3) as being obvious over Olsson et al (1997) and Cho-Chung et al (1993). The claims are drawn to methods of diagnosing, staging and monitoring the metastatic potential of prostate cancer by identifying or detecting an increase in CSGs or cancer specific genes, in a patient wherein the CSGs comprise the SEQ IDs recited in the claims. The claims are also drawn to a method of identifying therapeutic agents that bind to the said CSGs. Olsson et al teach the diagnosis, staging, monitoring metastasis of prostate cancer. Olsson et al teach that tumor cells exhibit abnormally rearranged or mutated genes that are not present in normal cells (these can be considered cancer specific genes). Olsson et al teach RT-PCR as well as quantitative RT-PCR technology as applicable to the above mentioned methods, and applying the technology to various tissue and body fluid samples.

Cho-Chung et al teach the use of nucleic acid in the therapy of neoplasia with specific reference to anti-sense oligonucleotides. (Continued on Supplemental Sheet.)

International application No. PCT/US99/24331

Supp	lem	ente	ı	Rox

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below: IPC(7): A61K 39/395, 48/00; C12P 19/34; C12Q 1/68; G01N 33/53, 33/574, 33/546, 33/567 and US C1.: 424/130.1, 141.1, 155.1, 183.1; 435/6, 7.1, 7.23, 7.9, 91.2; 436/501, 504, 505, 547; 514/44; 536/23.5

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):

The disclosure of Cho-Chung et al inherently teaches a method of identifying potential candidates that will bind to the CSGs in prostate cancer. Though the above cited art do not specifically mention the SEQ ID Nos, it would have been obvious to one of ordinary skill in the art at the time of the invention to extend the methods wherein the PSA or PMSA have been replaced with the SEQ ID Nos recited in the claims. One of ordinary skill in the art would have been motivated to do so because the prior art teaches that cancer specific genes include any genes that are expressed by cancer cells and not by normal cells. Absent any unexpected results by the inclusion of the SEQ ID Nos recited in the claims, the use of these sequences in a method of diagnosing, staging and monitoring the metastatic potential of prostate cancer would have been obvious to do f or one of ordinary skill ion the art.

*******	NEW	CITATIONS	
NONE			

PATENT COOPERATION TREAD

	From the INTERNATIONAL BUREAU
PCT	То:
NOTIFICATION OF ELECTION (PCT Rule 61.2)	Assistant Commissioner for Patents United States Patent and Trademark Office Box PCT Washington, D.C.20231 ETATS-UNIS D'AMERIQUE
Date of mailing (day/month/year) 08 June 2000 (08.06.00)	in its capacity as elected Office
International application No. PCT/US99/24331	Applicant's or agent's file reference DEX-0052
International filing date (day/month/year) 19 October 1999 (19.10.99)	Priority date (day/month/year) 19 October 1998 (19.10.98)
Applicant	15 Getaber 1555 (15.16.55)
SALCEDA, Susana et al	
The designated Office is hereby notified of its election made before the expiration of 19 months from the priority Rule 32.2(b).	y Examining Authority on: (09.05.00) national Bureau on:
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer C. Villet Telephone No.: (41-22) 338.83.38
1 4 4 5 5 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	10.0ph.010 140 (11-22) 000.00.00

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

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ΑZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
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BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
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PATENT COOPERATION TREATY 13 FE3 2001

PCT

WIPO PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference DEX-0052	FOR FURTHER ACTION	See Notifi Preliminary	ication of Transmittal of International Examination Report (Form PCT/IPEA/416)
International application No.	International filing date (day/r	nonth/year)	Priority date (day/month/year)
PCT/US99/24331	19 (18) OCTOBER 1999		19 OCTOBER 1998
International Patent Classification (IPC) Please See Supplemental Sheet.	or national classification and IP	С	
Applicant DIADEXUS LLC			
Examining Authority and is 2. This REPORT consists of a This report is also accompleen amended and are the	transmitted to the applicant a total of sheets. panied by/ANNEXES, i.e., shee	according to ets of the descreets containing	ription, claims and/or drawings which have g rectifications made before this Authority.
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3. This report contains indication		ems:	· · · · · · · · · · · · · · · · · · ·
I Basis of the repor	rt		
II Priority	•		
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III Non-establishmen	at of report with regard to no	velty, inventi	ive step or industrial applicability
IV Lack of unity of i	invention		
V X Reasoned statemen citations and explan	nt under Article 35(2) with regarations supporting such statem	ırd to novelty ent	, inventive step or industrial applicability;
VI Certain documents	cited		
VII Certain defects in the	ne international application		
VIII Certain observations	s on the international application	on	
Date of submission of the demand	Date	of completion	of this report
09 MAY 2000	19	JANUARY 2	2001
Name and mailing address of the IPEA/U	JS Authø	fized officer	
Commissioner of Patents and Tradema Box PCT		withe	Naurence Jos
Washington, D.C. 20231		EETHA P. BA	ANSAL /
Facsimile No. (703) 305-3230 Telephone No. (703) 308-0196			(03) 308-0196

International application No.

PCT/US99/24331

I. E	Basis	of the rep	ort						
1. W i	ih rega	urd to the ele	ements of the interna	ational applicati	on:*				
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	filed	together	with the internation	onal applicati	ion in comput	er readable forr	m.		
	furn	ished subs	equently to this A	Authority in v	vritten form.	•			
	furn	shed subs	equently to this A	Authority in c	omputer read	able form.			
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	The been	statement the furnished.	nat the information	recorded in co	omputer readab	le form is identic	al to the w	riten sequence listin	g has
4. X	The	amendme	nts have resulted	in the cancel	lation of:				
	X	the descr	ription, pages	NONE					
	X	the claim	ns, Nos.	NONE					
	X		ings, sheets/fig_	NONE					
5.	This			ome of) the am	endments had	not been made si	ince thev h	ave been considered	to go
			losure as filed, as i					John Johnson	60
in th	aceme	nt sheets whoort as "ori	ich have been furnis	shed to the rece	iving Office in i	esponse to an invi	tation under	r Article 14 are 🛮 refe amendments (Rules	erred to 70.16
			et containing such	amendments m	ust be referred	to under item 1	and annex	ed to this report.	

International application No.
PCT/US99/24331

V.	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicab	nility:
	citations and explanations supporting such statement	,,,,,

1. statement			
Novelty (N)	Claims Claims	<u>7</u> 1-6	YES
Inventive Step (IS)	Claims Claims	NONE 1-7	YES NO
Industrial Applicability (IA)	Claims Claims	1-7 NONE	YES

2. citations and explanations (Rule 70.7)

Claims 1-6 lack novelty under PCT Article 33(2) as being anticipated by Olsson et al (1997) and Cho-Chung et al (1993).

The claims are drawn to methods of diagnosing, staging and monitoring the metastatic potential of prostate cancer by identifying or detecting an increase in CSGs or cancer specific genes, in a patient. The claims are also drawn to a method of identifying therapeutic agents that bind to CSGs. Olsson et al teach the diagnosis, staging, monitoring metastasis of prostate cancer. Olsson et al teach that tumor cells exhibit abnormally rearranged or mutated genes that are not present in normal cells (these can be considered cancer specific genes). Olsson et al teach RT-PCR as well as quantitative RT-PCR technology as applicable to the above mentioned methods, and applying the technology to various tissue and body fluid samples.

Cho-Chung et al teach the use of nucleic acid in the therapy of neoplasia with specific reference to anti-sense oligonucleotides. The disclosure of Cho-Chung et al inherently teaches a method of identifying potential candidates that will bind to the CSGs in prostate cancer.

Claim 7 lacks an inventive step under PCT Article 33(3) as being obvious over Olsson et al (1997) and Cho-Chung et al (1993). The claims are drawn to methods of diagnosing, staging and monitoring the metastatic potential of prostate cancer by identifying or detecting an increase in CSGs or cancer specific genes, in a patient wherein the CSGs comprise the SEQ IDs recited in the claims. The claims are also drawn to a method of identifying therapeutic agents that bind to the said CSGs. Olsson et al teach the diagnosis, staging, monitoring metastasis of prostate cancer. Olsson et al teach that tumor cells exhibit abnormally rearranged or mutated genes that are not present in normal cells (these can be considered cancer specific genes). Olsson et al teach RT-PCR as well as quantitative RT-PCR technology as applicable to the above mentioned methods, and applying the technology to various tissue and body fluid samples.

Cho-Chung et al teach the use of nucleic acid in the therapy of neoplasia with specific reference to anti-sense oligonucleotides. (Continued on Supplemental Sheet.)

International application No.

PCT/US99/24331

Supp	lemen	tal	Box
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(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below: IPC(7): A61K 39/395, 48/00; C12P 19/34; C12Q 1/68; G01N 33/53, 33/574, 33/546, 33/567 and US Cl.: 424/130.1, 141.1, 155.1, 183.1; 435/6, 7.1, 7.23, 7.9, 91.2; 436/501, 504, 505, 547; 514/44; 536/23.5

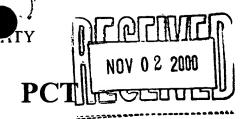
V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):

The disclosure of Cho-Chung et al inherently teaches a method of identifying potential candidates that will bind to the CSGs in prostate cancer. Though the above cited art do not specifically mention the SEQ ID Nos, it would have been obvious to one of ordinary skill in the art at the time of the invention to extend the methods wherein the PSA or PMSA have been replaced with the SEQ ID Nos recited in the claims. One of ordinary skill in the art would have been motivated to do so because the prior art teaches that cancer specific genes include any genes that are expressed by cancer cells and not by normal cells. Absent any unexpected results by the inclusion of the SEQ ID Nos recited in the claims, the use of these sequences in a method of diagnosing, staging and monitoring the metastatic potential of prostate cancer would have been obvious to do f or one of ordinary skill ion the art.

	NEW	CITATIONS	
NONE			

From the INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

JANE MASSEY LICATA



Applicant's or agent's file reference DEX-0052 International application No. International filing date (day/month/year) International application No. PCT/US99/24331 It is OCTOBER 1999 It is OCTOBER 1999 It is OCTOBER 1998 International Patent Classification (IPC) or both national classification and IPC Please See Supplemental Sheet. Applicant DIADEXUS LLC I. This written opinion is the first (first, etc.) drawn by this International Preliminery Examining Authority. 2. This opinion contains indications relating to the following items: I X Basis of the opinion II Priority III Non-establishment of opinion with regard to novelty, inventive step or industrial applicability IV Lack of unity of invention V X Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement VI Certain documents cited VII Certain defects in the international application VIII Certain observations on the international application 3. The applicant is hereby invited to reply to this opinion. When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.3(4). How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rule 66.4. For the examiner's obligation to consider amendments, see Rule 66.4. For the examiner's obligation to consider amendments, see Rule 66.4. For the examiner's obligation to consider amendments, see Rule 66.4. For the reaminer's obligation to consider amendments, see Rule 66.4. For an informal communication with the examiner, see Rule 66.6.	LAW OFFICES OF JANE MASSEY LICATA 66 E. MAIN STREET MARLTON, NEW JERSEY 08053			WRITTEN OF	
DEX-0052 International application No. International filing date (day/month/year) Priority date (day/month/year) 19 OCTOBER 1998 19 OCTOBER 1998	Docket System Status Report Docket Book 11/25/00 ANS				
International application No. PCT/US99/24331 Is OCTOBER 1999 International Patent Classification (IPC) or both national classification and IPC Please See Supplemental Sheet. Applicant DIADEXUS LLC I. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority. 2. This opinion contains indications relating to the following items: I X Basis of the opinion II Priority III Non-establishment of opinion with regard to novelty, inventive step or industrial applicability IV Lack of unity of invention V X Reasoned statement under Rule 66.2(a(Xii)) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI Certain documents cited VII Certain defects in the international application VIII Certain observations on the international application 3. The applicant is hereby invited to reply to this opinion. When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to great an extension, see Rule 66.3(d). How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9. Also For an additional opportunity to submit amendments, see Rules 66.4 bis. For an informal communication with the examiners, see Rule 66.6.	Applicant's or agent's file reference		REPLY DUE	ithin ONE month	•
International Patent Classification (IPC) or both national classification and IPC Please See Supplemental Sheet. Applicant DIADEXUS LLC 1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority. 2. This opinion contains indications relating to the following items: 1	DEX-0052				=
International Patent Classification (IPC) or both national classification and IPC Please See Supplemental Sheet. Applicant DIADEXUS LLC 1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority. 2. This opinion contains indications relating to the following items: 1	International application No.	International filing date	(day/month/year)	Priority date (day	y/month/year)
Please See Supplemental Sheet. Applicant DIADEXUS LLC 1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority. 2. This opinion contains indications relating to the following items: I X Basis of the opinion II Priority III Non-establishment of opinion with regard to novelty, inventive step or industrial applicability IV Lack of unity of invention V X Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI Certain documents cited VII Certain defects in the international application VIII Certain observations on the international application 3. The applicant is hereby invited to reply to this opinion. When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d). How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9. Also For an additional opportunity to submit amendments, see Rules 66.4 bis. For an informal communication with the examiner, see Rule 66.4.	PCT/US99/24331	18 OCTOBER 1999	19 OCTOBER 1998		R 1998
1. This written opinion is the first (first, etc.) drawn by this International Preliminery Examining Authority. 2. This opinion contains indications relating to the following items: 1		or both national classific	ation and IPC		
2. This opinion contains indications relating to the following items: I	1				
4. The final date by which the international preliminary examination report will be established on the basis of this opinion. 4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 19 FEBRUARY 2001	I X Basis of the opinion II Priority III Non-establishment of IV Lack of unity of inve V X Reasoned statement of citations and explanar VI Certain documents of VII Certain observations 3. The applicant is hereby invited to re When? See the time limit in Authority to grant and How? By submitting a write for the form and the Also For an additional op For the examiner's of For an informal com If no reply is filed, the internation 4. The final date by which the internation	opinion with regard to ention under Rule 66.2(a)(ii) witions supporting such stated international application on the international application on the international applicated above. The applicated above. The application of the amendation of the amendational preliminary examinational preliminary	ith regard to novelty, atement ication ication ication where appropriate, become appropriate, becoments, see Rules 66. indments, see Rule 66. ication and/or arguments, see Rule 66. ication report will be est	expiration of that y amendments, ac 8 and 66.9. i.4. uments, see Rule 6. ablished on the ba	time limit, request this ecording to Rule 66.3.

Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer Suurence Joseph GEETHA P. BANSAL
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0196

WRITTEN OPINION

International application No.

PCT/US99/24331

I. Basis of the opinion							
1 11/2	th managed	to the elements of the international applicati	ion:#				
X the international application as originally filed							
х		•	, as originally filed				
	pages		, filed with the demand				
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<u> </u>			an ariginally filed				
			, as originally filed , as amended (together with any statement) under Article 19				
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x	1 the se	quence listing part of the description:					
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	pages	NONE	, filed with the demand				
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the	internations internations in the last	ional application was filed, unless otherwi ents were available or furnished to this Au nguage of a translation furnished for t nguage of publication of the internation guage of the translation furnished for the	above were available or furnished to this Authority in the language in which ise indicated under this item. which is: thority in the following language which is: the purposes of international search (under Rule 23.1(b)). onal application (under Rule 48.3(b)). purposes of international preliminary examination (under Rules 55.2 and/				
	_	d to any nucleotide and/or amino acid as the basis of the sequence listing:	equence disclosed in the international application, the written opinion was				
contained in the international application in printed form.							
Г	filed together with the international application in computer readable form.						
一	furnished subsequently to this Authority in written form.						
	furnished subsequently to this Authority in computer readable form.						
늗	The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the						
international application as filed has been furnished.							
Ļ	The statement that the information recorded in computer readable form is identical to the writen sequence listing has been furnished.						
4 X	4 X The amendments have resulted in the cancellation of:						
7.	V NONE						
	the description, pages						
		the claims, Nos. NONE the drawings, sheets/fig NONE	· · · · · · · · · · · · · · · · · · ·				
5.	¬—		amendments had not been made, since they have been considered to go				
ے، <u>ا</u>		nd the disclosure as filed, as indicated in the					
•		t sheets which have been furnished to the re on as "originally filed".	eceiving Office in response to an invitation under Article 14 are referred to				

WRITTEN OPINION

International application No.

PCT/US99/24331

Claims 1-6 N	statement			
Industrial Applicability (IA) Claims Claims 1-7 Claims NONE Industrial Applicability (IA) Claims 1-7 Claims NONE Claims 1-7 NONE N Claims 1-6 lack novelty under PCT Article 33(2) as being anticipated by Olsson et al (1997) and Cho-Chung et al (1993). The claims are drawn to methods of diagnosing, staging and monitoring the metastatic potential of prostate cancer by identifying or detecting an increase in CSGs or cancer specific genes, in a patient. The claims are also drawn to a method of identifying the repeutic agents that bind to CSGs. Olsson et al teach the diagnosis, staging, monitoring metastasis of prostate cancer. Olssot et al teach that tumor cells exhibit abnormally rearranged or mutated genes that are not present in normal cells (these can be debove mentioned methods, and applying the technology to various tissue and body fluid samples. Cho-Chung et al teach the use of nucleic acid in the therapy of neoplasia with specific reference to anti-sense oligonucleotide. The disclosure of Cho-Chung et al inherently teaches a method of identifying potential candidates that will bind to the CSGs prostate cancer. Claims 7 lacks an inventive step under PCT Article 33(3) as being obvious over Olsson et al (1997) and Cho-Chung et al (1993). The claims are drawn to methods of diagnosing, staging and monitoring the metastatic potential of prostate cancer by identifying or detecting an increase in CSGs or cancer specific genes, in a patient wherein the CSGs comprise the SEQ IDs recited in the claims. The claims are also drawn to a method of identifying therapeutic agents that bind to the said CSGs. Olsson et al teach RT-PCR as well as quantitative RT-PCR technology as applicable to the above mentioned methods, and applying the technology to various tissue and body fluid samples. Cho-Chung et al teach the use of nucleic acid in the therapy of neoplasia with specific reference to anti-sense	Novelty (N)	Claims	7	Y.
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WRITTEN OPINION

International application No.

PCT/US99/24331

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Continuation of: Boxes I - VIII

Sheet 10

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below: IPC(7): A61K 39/395, 48/00; C12P 19/34; C12Q 1/68; G01N 33/53, 33/574, 33/546, 33/567 and US Cl.: 424/130.1, 141.1, 155.1, 183.1; 435/6, 7.1, 7.23, 7.9, 91.2; 436/501, 504, 505, 547; 514/44; 536/23.5

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):

The disclosure of Cho-Chung et al inherently teaches a method of identifying potential candidates that will bind to the CSGs in prostate cancer. Though the above cited art do not specifically mention the SEQ ID Nos, it would have been obvious to one of ordinary skill in the art at the time of the invention to extend the methods wherein the PSA or PMSA have been replaced with the SEQ ID NOs recited in the claims. One of ordinary skill in the art would have been motivated to do so because the prior art teaches that cancer specific genes include any genes that are expressed by cancer cells and not by normal cells. Absent any unexpected results by the inclusion of the SEQ ID Nos recited in the claims, the use of these sequences in a method of diagnosing, staging and monitoring the metastatic potential of prostate cancer would have been obvious to do for one of ordinary skill ion the art.

NONE N	EW CITATIONS	

INTERNATIONAL SEARCH REPORT

International application No. PCT/US99/24331

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A. CL	ASSIFICATION OF SUBJECT MATTER :Please See Extra Sheet		_		
US CL	:Please See Extra Sheet,				
According	to International Patent Classification (IPC) or to bo	th national classification and IPC			
	LDS SEARCHED				
Minimum 9	documentation searched (classification system follo	wed by classification symbols)			
U.S. :	424/130.1, 141.1, 155.1, 183.1; 435/6, 7.1, 7.23,				
Documenta	ation searched other than minimum documentation to	the extent that such documents are included	in the fields searched		
Electronic	data base consulted during the international search	(name of data base and, where practicable	, search terms used)		
Medline, search ter	Biosis, Embase, Cancerlit, Scisearch, WPIDS, USP rms: CSG, cancer specific gene, cancer, diagnosis	ATFULL			
C. DOC	CUMENTS CONSIDERED TO BE RELEVANT				
Category*	Citation of document, with indication, where	appropriate, of the relevant passages	Relevant to claim No.		
Y	Database SCISEARCH, Accession N	umber 307617. OLSSON et al.	1-6		
	Reverse transcriptase-polymerase cha	in reaction assays for prostate	. (4)		
	cancer. Urologic Clinics of North An	nerica. May 1997, Vol. 24 No.			
	2, pages 367-&.				
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Y	CHO-CHUNG et al. Antisense Oligor	nucleotides for the treatment of	1-6		
	cancer. Current Opinion in Therapeu	tic Patents, 1993, Vol. 3, No.	1-0		
	12, pages 1737-1750, see entire docu	ment.			
A,E	BUSSEMAKERS et al. DD3: A new	prostate-specific gene, highly	1-7		
	overexpressed in prostate cancer. C	ancer Research. 01 December			
	1999, Vol. 59, No. 23, pages 5975-5	1979.			
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Furthe	er documents are listed in the continuation of Box (C. See patent family annex.			
· · · · · · · · · · · · · · · · · · ·	cial categories of cited documents:	"T" later document published after the inter- date and not in conflict with the applic	national filing date or priority ation but cited to understand		
to b	ument defining the general state of the art which is not considered to of particular relevance	the principle or theory underlying the i	nvention		
	ier document published on or after the international filing date	"X" document of particular relevance; the considered novel or cannot be considered			
crtec	ument which may throw doubts on priority claim(s) or which is d to establish the publication date of another citation or other risk reason (as specified)	"Y" document of particular relevance: the			
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. West	113	being obvious to a person skilled in the			
the p	ment published prior to the international filing date but later than priority date claimed	*& document member of the same patent f	amily ·		
ate of the a	ctual completion of the international search	Date of mailing of the international search	th report		
10 FEBRU	ARY 2000	07 MAR 2000			
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Authorized offices GEETHA P. BANSAL					
Box PCT Washington,	•	GEETHA P. BANSAL	,		
acsimile No.		Telephone No. (703) 308-0196			

INTERNATIONAL SEARCH REPORT

International application No. PCT/US99/24331

A. CLASSIFICATION OF SUBJECT MATTER: IPC (7):

A61K 39/395, 48/00; C12P 19/34; C12Q 1/68; G01N 33/53, 33/574, 33/546, 33/567

A. CLASSIFICATION OF SUBJECT MATTER: US CL :

424/130.1, 141.1, 155.1, 183.1; 435/6, 7.1, 7.23, 7.9, 91.2; 436/501, 504, 505, 547; 514/44; 536/23.5

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